

AS
the handpiece body has a fluid path in fluid communication with the fluid path of the tip, said handpiece body fluid path extending to the exterior of the handpiece, whereby fluid in the eye may flow through the tip and the handpiece body while laser light from the laser source is directed by the optical fiber into the eye.

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21. (Amended) The laser delivery system as set forth in claim 17 further including means for refluxing material drawn into [in] the fluid path from the eye back into the eye.

31. (Amended) The method as set forth in claim 30 wherein the [material is] aspirating step includes aspirating subretinal fluid [which is aspirated] out of the eye through the probe.

REMARKS

Claims 1 - 29 were rejected for improper antecedent basis for the terms "the proximal end" and "the distal end." Claims 1 and 17, the claims containing these phrases are amended herewith to add antecedent basis.

Claim 31 was rejected for failure to further limit the subject matter of a previous claim. It is herewith amended to put the limitation of that claim in proper method form.

Claim 30 was rejected under §102(b) as anticipated by Zelman. It is respectfully submitted that the Examiner has misread Zelman. Claim 30 provides for (1) inserting the distal end of a probe into the interior of an eye; (2) aspirating material out of the interior of the eye through the probe; and

(3) applying laser energy through the probe into the interior of the eye, without replacing said probe. Zelman teaches something very different. Zelman teaches the use of two separate devices, a probe 22 and a laser 24. The laser energy in Zelman is not applied through the probe as the present claim requires. Moreover, the laser energy is not applied in Zelman without replacing the probe.

Instead Zelman teaches first applying the laser energy using laser 24, and then aspirating material using separate probe 22. This teaching is highlighted by the statements in Zelman that (1) "Considerable time, a week or more, may pass between softening and removal." (col. 3, lines 21 - 22) and (2) "The end 20 of tube 22 is then manipulated adjacent to the cataract tissue which has already been softened and substantially fragmented by the previous application of laser radiation." (col. 3, lines 9 - 12). If laser 24 in Zelman were located in tube 22 (and there appears to be not a hint of such a construction in Zelman), there would be no reason for manipulating the tube 22 adjacent the tissue to be aspirated, since it would already be in place. These passages of Zelman teach directly away from applying laser energy through the probe without replacing the probe.

Claim 30 is clearly not anticipated by Zelman. In fact, the teaching of Zelman is directly the opposite, teaching the use of two devices at widely spaced times. Claim 30 is allowable over this art.

Claims 1 - 3, 14, 15, 17, 18, 20 and 29 were rejected under §102(e) as anticipated by Taboada et al. This rejection must fall since the claimed invention differs substantially from the device of Taboada et al.

Claim 1 requires a number of elements including (1) a handpiece with a handpiece body (which the user uses to hold and manipulate the handpiece) and a hollow tip of a size suitable for insertion into a human eye; (2) a laser connector for connection directly to a laser source; (3) an optical fiber extending between the laser connector and the handpiece, which optical fiber forms a lenseless optical path for transmitting laser light from the laser source to an eye to be treated; (4) the optical fiber extending through the handpiece body and at least partially through the handpiece tip; (5) the tip having a fluid path from its distal end to the interior of the handpiece body; and (6) the handpiece body having a fluid path in fluid communication with the fluid path of the tip.

Taboada et al. lacks many of these elements. For example, the handpiece body in Taboada et al. must be element 20 (since that is the element held and manipulated by the user), while the tip must be element 80 (Fig. 14) or element 95 (Fig. 17). Although the laser connector for connection directly to a laser source is not shown in Taboada et al., it must be the proximal end of element 21 in Taboada et al. Given those facts, Taboada et al. completely lacks the claimed optical fiber. Taboada et al. discloses and teaches a quartz rod which

originates and terminates in the handpiece tip. The claimed optical fiber, on the other hand terminates distally in the handpiece tip, but terminates proximally in the laser connector (which is connected directly to the laser source). The claimed optical fiber is also defined as extending through the handpiece body. The quartz rod in Taboada et al. is not disposed in the handpiece body at all. ^{Not true. See Fig 14}

Claim 1 further requires that the optical fiber be such as to form a lenseless optical path between the laser source and the eye to be treated. Taboada et al. discloses a number of lenses (81, 27, 29) in the optical path between the laser source "S" in Taboada et al. and the eye to be treated.

Taboada et al. also appears to lack the claimed fluid path from the distal end of the handpiece tip to the interior of the handpiece body 20. The only showing of the complete fluid path in Taboada et al. (including the proximal position of such a fluid path) is in Fig. 14, which shows a pair of fluid paths which run the length of the handpiece tip, but never enter the interior of handpiece body 20. ^{89 does} In this regard, Taboada et al. teaches directly away from the presently claimed invention.

For all these reasons, claim 1 is allowable over Taboada et al.

Claim 2 depends from claim 1 and provides that the handpiece body fluid path includes a cavity inside the handpiece body and a port connecting the cavity to the exterior of the handpiece, which cavity is larger in cross-section than the fluid

path in the handpiece tip. Taboada et al. does not show such an enlarged cavity forming part of the fluid path. It is allowable for this reason as well.

Claim 3 has been rewritten to be in independent form. In addition to including the elements of original claim 1, many of which are discussed above, it includes the element of means for refluxing material drawn into the fluid path from the eye back into the eye. This reflux feature is described on page 10 of the present application (first full paragraph) as follows:

"On occasion, distal tip 25 can suction in undesired material, such as a portion of the retina. With the present construction, this material can easily and rapidly be refluxed back into the eye, again with a one-handed operation. . . . By pressing downwardly on sleeve 23 above cavity 35, the surgeon applies pressure on the fluid path from port 37 through the distal end of tip 25. This pressure forces any undesired material back out of the distal end of tip 25."

Taboada et al. appears to be totally incapable of performing this claimed reflux action. If material is suctioned into fluid path 88 (or 98) in Taboada et al., there is absolutely no way disclosed or taught in the reference to reflux that material back into the eye. Taboada et al., therefore, teaches directly away from the present invention on this feature.

Claim 3 is allowable for this reason as well.

Claim 14 also depends from claim 1 and is allowable with that claim. In addition, this claim provides that the optical fiber is fixedly secured to the handpiece body and is otherwise loosely disposed in the handpiece tip. This is exactly the opposite of what is taught in Taboada et al. in which the quartz rod is fixed in the handpiece tip. Claim 14 is allowable for this reason as well.

Claim 15 is amended herewith to provide that an intermediate portion of the optical fiber is removably securable in a fixed position with respect to the operating field, which intermediate portion is disposed exteriorly of the handpiece. The means for accomplishing this feature is clamp 29. Taboada et al. is incapable of providing such means, since the quartz rod in Taboada et al. is wholly disposed in the handpiece (specifically in the handpiece tip). Taboada et al., therefore, has no means for removably securing an intermediate portion of the optical fiber to any position exterior of the handpiece. Claim 15 is allowable for this reason, as well as for the same reasons as claim 1, from which it depends.

Claim 17 is an independent claim which includes the claimed optical fiber, described above in connection with claim 1, as well as the securing means described above in connection with claim 15. For the corresponding reasons set forth above with respect to those claims, claim 17 is allowable over Taboada et al.

Claim 18 depends from claim 17 and further provides that the removably securing means is a clamp. Taboada et al. is completely silent concerning such a clamp. Claim 18 is allowable for this reason as well.

Claim 20 also depends from claim 17 and further specifies the fluid path from the handpiece tip to the interior of the handpiece body. As explained above in connection with claim 1, Taboada et al. does not show or suggest a fluid path into the interior of the handpiece body. Claim 20 is also allowable for this additional reason.

Claim 29 depends from claim 17 and adds the feature that the optical fiber is fixedly secured to the handpiece body and is otherwise loosely disposed in the handpiece tip. As explained above in connection with claim 14, Taboada et al. teaches exactly the opposite, fixedly securing the quartz rod in the handpiece tip. Claim 29 is allowable for this reason as well.

Claims 4, 6, 13, 21, 22, and 24 are rejected under §103 over Hasson in view of Reynolds et al. Hasson is directed to a laser surgical device which is designed for use in body cavities such as the uterus. It has no hint that such a structure may be used ⁱⁿ the confines of a human eye as required by claims 1 and 17 from which these claims depend. Moreover, claim 4 depends from claim 3 which requires means for refluxing material drawn into the fluid path from the eye back into the eye. Ignoring for the moment the non-analogous nature of Hasson, it completely lacks the reflux feature of claim 3. Once material is drawn into

opening 64 in Hasson, there is apparently no way to reflux that material back out of opening 64 into the body cavity as required by claim 3. Hasson, therefore, teaches against the presently claimed refluxing feature. Moreover, claim 4 requires that the refluxing means be included in the handpiece body. Hasson, which wholly lacks such a refluxing means, is silent concerning positioning such a refluxing means in the handpiece body.

Nor does Reynolds et al. disclose such a refluxing means, contrary to the Examiner's assertion. Reynolds et al. teaches a fluid path which adds anticoagulant to blood which is being aspirated, but is apparently silent concerning any way to reflux that aspirated blood or anything else back out of the fluid path once it has been drawn into the fluid path. Moreover, Reynolds et al. is non-analogous art since it is directed to metering anticoagulant to aspirated blood for autologous blood transfusions. It should be appreciated that the amount of blood involved in Reynolds et al. is vastly greater than that encountered in ophthalmic surgery, and the problems and scale of each are vastly different.

For all these reasons, claim 4 is allowable over the cited art.

Similarly, claim 6 depends from claim 3 and further provides that the refluxing means is manually operable. The cited art, which apparently completely lack the claimed reflux feature, therefore lack the manually operable refluxing means of this claim.

Claim 13 depends from claim 1. Claim 13 further provides that the handpiece body fluid path cavity is larger in cross-section than the fluid path in the handpiece tip. It is not believed that either Hasson or Reynolds et al. shows such an enlarged cavity. Claim 13 is allowable for this reason as well.

Claim 21 depends from claim 17 and provides for the refluxing means. As pointed out above, to the extent that Hasson and Reynolds et al. are considered relevant by the Examiner, they utterly fail to show this claimed reflux feature.

Claim 22 depends from claim 21 and requires that the handpiece body includes the refluxing means. It is therefore allowable for essentially the same reasons as claim 4.

Claim 24 also depends from claim 21 and provides that the refluxing means is manually operable. It is allowable for essentially the same reasons as claim 6.

Claim 13 is rejected under §103 over Hasson in view of Taboada et al. Claim 13 depends from claim 1. The differences between Taboada et al. and claim 1 are outlined above. In addition this claim provides that the handpiece fluid path cavity is enlarged as explained above. Neither of these references shows such a feature. Claim 13 is allowable over these references for this reason as well.

Claims 32 and 33 are rejected under §103 over the present disclosure in view of Zelman. These claims relate back to claim 30. As explained above, the Examiner's rejection of that claim based on Zelman is grounded on a misreading of that

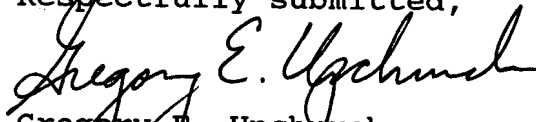
reference. With respect to claim 32, which requires aspirating subretinal fluid after application of laser energy without replacing the probe, Zelman (as explained above) clearly teaches away from "without replacing the probe." Similarly, claim 33, which requires simultaneously aspirating blood from the interior of the eye and coagulating surface bleeding using laser energy, is neither shown nor suggested by Zelman which teaches replacing the laser 24 with probe 22. Claims 32 and 33 are allowable for these reasons as well.

The allowability of claims 34 - 36, and 5 - 12, 19, 23, and 25 - 28 is acknowledged.

In view of the above, favorable reconsideration and a Notice of Allowability of claims 1 - 36 is solicited.

A check in the amount of \$48.00 for new independent claim 3 is enclosed.

Respectfully submitted,



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